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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,500	12/11/2001	Maria Kordowicz	MERCK 2332	4910
23599	7590	03/02/2005	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/009,500

Applicant(s)

KORDOWICZ ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12, 14-17 and 21-24 is/are allowed.
- 6) ☒ Claim(s) 13 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Applicants argue that because the proteins of SEQ ID NO:1, 3, 5 and 7 share 93% identity, that these claims should be examined together and the previous restriction requirement should be withdrawn. After careful consideration of the exhibit submitted with this amendment the examiner hereby drops the restriction requirement. The examiner will examine claims 1-24.

The disclosure is objected to because of the following informalities:

In the amendment to page 28, applicants have left two copies of the sequence starting with "119" in the specification, the original one and the added one. This is confusing and incorrect. The way applicants amended the specification is not what was envisioned by 37 CFR § 1.121. The instant section states that:

(b)(1) The full text of any replacement paragraph with markings... [should be presented] to show all the changes relative to the previous version of the paragraph. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived.

Applicants have lined though all of the text of each paragraph to be changed (except for the recitation on page 28 mentioned *supra*) and then reprinted the text with underlining. What was envisioned was to reprint the paragraph with only deletions lined though and only additions underlined, as was done by applicants in their amendments to the claims. The way the instant amendment was made makes it is extremely difficult to determine what was added and deleted from the paragraph. The examiner believes he understands all of the amendments made.

Appropriate correction is required.

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Claims 13 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is confusing in the recitation of "having any amino acid sequence depicted in Fig. 8, 9 and 10 (SEQ ID Nos 3, 4, 7)". The instant claim reads on a protein having an amino acid sequence having the sequence depicted in "Fig. 8, 9 and 10". It is not clear from the claim language which sequence or combination of sequences the protein is limited to. Changing the instant recitation to "having any amino acid sequence selected from the group consisting of the sequence depicted in Fig. 8, 9 and 10 (SEQ ID Nos 3, 4 and 7)" or "having any amino acid sequence depicted in Fig. 8, 9 or 10 (SEQ ID Nos 3, 4 or 7)" would overcome this rejection or some similar recitation would overcome this rejection.

Claim 18 is indefinite and confusing in the recitation of "additionally". The claim does not recite any substance before this and therefore the recitation "additionally" does not make any sense. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection. It is stated by applicants that "[c]laims...18, and 19 have been amended to clarify them" but no such amendment has been made.

Claims 18 and 19 are indefinite in that they do not depend upon any other claim and therefore read on any and all pharmaceutical compositions in the world. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection. It is stated by applicants that "[c]laims...18, and 19 have been amended to clarify them" but no such amendment has been made.

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Claim 20 is confusing in the recitation of "comprising administering to a subject in need of a protein of claim 1". The instant claims language does not include a step of administering the protein but simply states that the "subject [is] in need of a protein of claim 1". The recitation of "comprising administering to a subject in need of the protein a protein of claim 1" or some similar recitation would overcome this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim reads on a sequence having at least 80% homology to SEQ ID NO:3, 5 or 7. The specification does not teach one of ordinary skill in the art to make and/or use such a protein but instead teaches this ordinary artisan to make SEQ ID NO:3, 5 or 7. In order to allow for allelic variants the examiner will allow claims drawn to 95% homology.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18 and 19 are rejected under 35 U.S.C. 102(b or e) as being anticipated by either of Wnendt, et al. (A) or Jones, et al. (AC). This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection. Applicants state that "[it] is believed that amendment to claim 18 renders this rejection moot", but as discussed *supra* in the 35 USC § 112 second paragraph rejection, no amendment has been made to claim 18.

Claims 1-12, 14-17 and 21-24 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status informa-

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tion for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
February 25, 2005